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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,524	02/11/2004	Gosse Jan Adema	DX0670KB1B	8025

28008 7590 08/07/2007

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EXAMINER	
BUNNER, BRIDGET E	
ART UNIT	**PAPER NUMBER**
1647	
MAIL DATE	**DELIVERY MODE**
08/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,524	ADEMA ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21 and 23-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21 and 23-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20070503*.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

Claims 21 and 23-29 are under consideration in the instant application.

Claim Rejections - 35 USC § 101 and 35 U.S.C. § 112, first paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 21 and 23-29 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation. The basis for this rejection is set forth for claims 21 and 23-29 at pg 3-14 of the previous Office Action (27 December 2006), page 4-9 of the Office Action of 05 April 2006 and for claims 21-29 at pg 3-6 of the Office Action of 12 July 2005.

The claims are directed to a substantially pure or isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 2. The claims recite a composition comprising the polypeptide and a polypeptide fused to a detection or purification tag. The claims recite a kit comprising the polypeptide. The claims recite that the polypeptide is recombinantly produced.

Applicant's arguments (27 June 2007), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

(i) At page 3 of the Response of 27 June 2007, Applicant states that the Examiner appears to be relying heavily on *in re Fisher* 421 F.3d 1365 (2005), a case whose facts are easily distinguishable from the current application. At page 3 through the top of page 4 of the Response, Applicant reviews the facts of *in re Fisher*.

The Examiner takes no issue with Applicant's general comments regarding the legal standard for utility..

(ii) At the middle of page 4 of the Response, Applicant argues that the specification meets the standard discussed in *Fisher* by disclosing more than merely a generic utility for FDF03 as well as providing evidence that the asserted utilities are significant and have a presently available benefit to the public. Applicant points out that the specification at page 68 through page 69 disclosed that the FDF03 protein "likely plays a role in regulation or development of hematopoietic cells, ...e.g., antigen presentation and the resulting effector functions". Applicant asserts that the evidence demonstrates that FDF03 does indeed play a role in the regulation in mast cells and antigen presenting cells. Applicant argues that the specification further discloses FDF03 as a cell surface marker that is discretely and specifically expressed on cells of the myelomonocytic lineage, e.g., monocytes (page 54, lines 18-22; page 87, lines 35 through page 88, line 6). Applicant contends that these are specific and substantial utilities that are supported by copious evidence already of record. Applicant adds that the evidence shows that the asserted utilities were accurate as disclosed in the specification and immediately useful. Applicant states that the very specific, disclosed utilities cannot be construed as being generic or without

immediate benefit to the public as such a use cannot be assigned to just any new protein or even any new protein expressed on antigen presenting cells.

Applicant's arguments have been fully considered but are not found to be persuasive. The specification does not teach any methods or working examples to demonstrate that the FDF03 polypeptide of the instant application has any functional activity. At the time the instant application was filed, one skilled in the art would not have known the utility and function of polypeptide in the instant specification, even if it was a putative Ig receptor expressed on monocytes and dendritic cells because, as discussed in the related art (see Huang et al., Biopolymers 43: 367-382, 1997), immunoglobulin superfamily members include a wide range of receptors with diverse biological activities. Basic research to determine the functional properties of the claimed protein is still required. Although the specification discloses that "[t]he proteins likely play a role in regulation or development of hematopoietic cells, e.g. lymphoid cells, which affect immunological responses, e.g. antigen presentation and the resulting effector functions" (pg 68, line 37 through pg 69, lines 1-3), this asserted utility is not specific or substantial because it is not clear what specific role or function FDF03 is correlated with (such as proliferation, differentiation, apoptosis, cell-cell adhesion, regulation of cytokine production, T cell activation, antigen capture and presentation, among others) or which specific hematopoietic cells FDF03 regulates or develops. Absent such identification, the FDF03 polypeptide has not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent.

As discussed in the previous Office Actions of 27 December 2006 and 05 April 2006, the specification at the time of filing does not disclose that FDF03 is involved in antigen

presentation or negatively regulates activation of dendritic cells and monocytes. The specification at the time of filing also does not disclose that FDF03 is an inhibitory receptor or any physiological activity of FDF03. Although the post-filing date references, which study FDF03, are interesting, they clearly indicate that at the time of filing, further characterization of FDF03 was required and Applicant's invention was incomplete. As stated in *In re Fisher,* "[A]n application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research" (see *Fisher*, 421 F.3d at 1371, 76 USPQ2d at 1230; see also MPEP § 2107.01(B)). Additionally, the asserted patentable utility of using FDF03 as a marker to identify dendritic cells or cells of myelomonocytic lineage is not specific or substantial because the instant application does not disclose the biological role of the FDF03 protein or its significance. One skilled in the art would not readily use the polypeptide as a cell marker in a real world sense since the protein has not been shown to be specific to limited cell types and is not associated with any disease or disorder. The specification of the instant application only teaches that FDF03 is expressed on the cell surface of monocytes and dendritic cells. The specification does not disclose if there is differential expression of FDF03 on normal cells vs. cells of a disease/disorder. The specification and post-filing date references also do not provide any evidence to indicate that FDF03 *is not* expressed on other cells of the immune system, such as stem cells, progenitor cells, stromal cells, eosinophils, basophils, megakaryocytes, just to name a few. There is also no indication in the specification that neutrophils, which are derived from a monocyte progenitor cell, express FDF03. In other words, the specification does not teach definitive differential cell expression of FDF03. Thus, if one skilled in the art was to perform a cell separation technique on a blood sample using FDF03

as a marker, he/she may not simply isolate myelomonocytic cells or dendritic cells, as asserted by Applicant. Furthermore, evidence of mere expression on a tissue or cell type is not tantamount to a showing of a functional role of the FDF03 polypeptide. Basic research to determine the functional properties of the claimed protein is still required. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

In the instant case, the claimed FDF03 polypeptide is not disclosed as having an activity that can be specifically useful. Thus, further research is required to identify or reasonably confirm a specific and substantial utility. See MPEP § 2107.01(I)(C), for example. Such further research requirements make it make it clear that the asserted utility is not yet in currently available form, i.e., it is not substantial. This further experimentation is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. See *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct., 1966), wherein the court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", "Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

(iii) At the bottom of page 4 of the Response of 27 June 2007, Applicant asserts that there is no legal requirement for empirical evaluation or that a certain level of specificity regarding the role or function of a protein must be achieved. Applicant argues that there is no requirement for definitive evidence and disclosure of a detailed biologic profile to satisfy the utility requirement.

Applicant states that the utility must merely be capable of providing some identifiable benefit. Applicant submits that any of the utilities disclosed for the FDF03 satisfies this standard.

Applicant's arguments have been fully considered but are not found to be persuasive. A specification can meet the legal requirements of utility and enablement for a new polypeptide as long as the specification discloses at least one specific and substantial asserted utility for the new polypeptide, or a well-established utility for the claimed polypeptide that would be *prima facie* obvious to the skilled artisan. However, the instant disclosure of a novel immunoglobulin superfamily member fails to provide any factual evidence that this specific FDF03 polypeptide is associated with any particular disease, condition, or physiological process.

The specification at the time of filing does not disclose that FDF03 negatively regulates activation of dendritic cells and monocytes. The specification at the time of filing also does not disclose that FDF03 is an inhibitory receptor or any physiological activity of FDF03. Although the post-filing date references, which study FDF03, are interesting, they clearly indicate that at the time of filing, further characterization of FDF03 was required and Applicant's invention was incomplete.

2. Claims 21 and 23-29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The basis for this rejection is set forth for claims 21 and 23-29 at page 14 of the previous Office Action (27 December 2006), at pg 9 of the previous

Office Action of 05 April 2006 and for claims 21-29 at pg 6 of the Office Action of 12 July 2005.

Applicant's arguments (27 June 2007), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

Specifically, since Applicant has not provided evidence to demonstrate that the FDF03 polypeptide of SEQ ID NO: 2 has a specific and substantial asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention. It is noted that the instant specification is required to teach one skilled in the art how to make and use the FDF03 polypeptide.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB
Art Unit 1647
30 July 2007

Bridget E. Bunner

BRIDGET E. BUNNER
PRIMARY EXAMINER